JAN 8 2002

Attachment I
510(K) Summary
ProLite Pulsed Light System

K013366

This 510(K) Summary of safety and effectiveness for the ProLite Pulsed Light System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Medical Bio Care Sweden AB.
Address:	Lona Knapes gata 5 421.32 Vastra Frolunda, Sweden
Contact Person:	Morgan Gustafsson
Telephone / Fax / Email	46.31.709.30.70 – Phone 46.31.709.30.79 – Fax morgan@medicalbiocare.com
Preparation Date:	September 22, 2001
Device Trade Name:	ProLite Pulsed Light System
Common Name:	Pulsed Light for Photoepilation
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	EpiLight / Photoderm HR System K number K974536
Description of the ProLite Pulsed Light System	The ProLite Pulsed Light System delivers pulsed light at a wavelength beginning at a wavelength of 600 nm. The device consists of three interconnected sections: The cabinet which houses the internal cooling system, power sypply and microcontroller, the umbilical to the handpiece, and the handpiece, which houses the waveguide
Intended use of the ProLite Pulsed Light System	The ProLite Pulsed Light System is indicated for use to remove unwanted hair in all skin types according to the Fitzpatrick Scale.
Performance Data:	Clinical studies were conducted to provide assurance that difference in the specifications of the ProLite Pulsed Light System and the predicate device for hair removal did not result in different performance during use. These results were previously reported to the FDA in 510(K) 010927.

Results of Clinical Study:	Observation in the clinical study were recorded prior to treatment and at 3-6 months after treatment. There was no scarring in any subject. The study demonstrated that selective photothermolysis targeting melanin in the human hair follicle is an effective tool for hair removal.
Conclusion:	The ProLite Pulsed Light System is substantially equivalent to other existing pulsed light systems in commercial distribution for removal of hair in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medical BioCare Sweden AB
c/o Ms. Connie White Hoy
908 Stetson Street
Woodland, California 95776

JAN 0 8 2002

Re: K013366
Trade/Device Name: ProLite Pulsed Light System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 22, 2001
Received: October 10, 2001

Dear Ms. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: Pending K013366

Device Name: ProLite Pulsed Light System

Indications for Use:

The ProLite Pulsed Light System is intended to remove unwanted hair for all skin types according to the Fitzpatrick Scale.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013366

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)